Appln. No.: 10/698,076

Restriction Requirement Mailed On January 3, 2007 Response To Restriction Filed On March 5, 2007

## Amendments to the Claims:

 (Original) A pharmaceutical composition, comprising a pharmaceutically or veterinarily acceptable carrier, a first active agent and a second active agent effective to treat asthma, chronic obstructive pulmonary disease, or a respiratory or lung disease.

(a) the first active agent is a non-glucocorticoid steroid having the chemical formula

wherein the broken line represents a single or a double bond; R is hydrogen or a halogen; the H at position 5 is present in the alpha or beta configuration or the compound of chemical formula I comprises a racemic mixture of both configurations; and  $R^1$  is hydrogen or a multivalent inorganic or organic dicarboxylic acid covalently bound to the compound; a non-glucocorticoid steroid of the chemical formula

a non-glucocorticoid steroid of the chemical formula

wherein R1, R2, R3, R4. R5, R7, R8, R9, R10, R12, R13, R14 and R19 are independently H, OR, halogen, (C1-C10) alkyl or (C1-C10) alkoxy, R5 and R11 are independently OH, SH, H, halogen, pharmaceutically acceptable ester, pharmaceutically acceptable thioester, pharmaceutically acceptable thioether, pharmaceutically

pharmaceutically acceptable ether, pharmaceutically acceptable thioether, pharmaceutically 3069218\_1.DOC Atty. Docket No.: 30775-714.201

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acceptable inorganic esters, pharmaceutically acceptable monosaccharide, disaccharide or oligosaccharide, spirooxirane, spirothirane, -OSO2R20, -OPOR20R21 or (C1-C10) alky, R5 and R6 taken together are =0, R10 and R11 taken together are =0; R15 is (1) H, halogen, (C1-C10) alkyl, or (C1-C10) alkoxy when R16 is -C(O)OR22, (2) H, halogen, OH or (C1-C10) alkyl when R16 is halogen, OH or (C1-C10) alkyl, (3) H, halogen, (C1-C10) alkyl, (C1-C10) alkenyl, (C1-C10) alkynyl, formyl, (C1-C10) alkanoyl or epoxy when R16 is OH, (4) OR, SH, H, halogen, pharmaceutically acceptable ester, pharmaceutically acceptable thioester, pharmaceutically acceptable ether, pharmaceutically acceptable thioether, pharmaceutically acceptable inorganic esters, pharmaceutically acceptable monosaccharide, disaccharide or oligosaccharide, spirooxirane, spirothirane, -OSO2R20 or -OPOR20R21 when R16 is H, or R15 and R16 taken together are =O; R17 and R18 are independently (1) H, -OH, halogen, (C1-C10) alkyl or -( C1-C10) alkoxy when R6 is H OR, halogen. (C1-C10) alkyl or -C(O)OR22, (2) H, (C1-C10 alkyl), amino, ((C1-C10) alkyl)n amino-(C1-C10) alkyl, (C1-C10) alkoxy, hydroxy - (C1-C10) alkyl, (C1-C10) alkoxy - (C1-C10) alkyl, (halogen)m (C1-C10) alkyl, (C1-C10) alkanoyl, formyl, (C1-C10) carbalkoxy or (C1-C10) alkanoyloxy when R15 and R16 taken together are =O, (3) R17 and R18 taken together are =O; (4) R17 or R18 taken together with the carbon to which they are attached form a 3-6 member ring containing 0 or 1 oxygen atom; or (5) R15 and R17 taken together with the carbons to which they are attached form an epoxide ring; R20 and R21 are independently OH, pharmaceutically acceptable ester or pharmaceutically acceptable. ether; R22 is H, (halogen)m (C1-C10) alkyl or (C1-C10) alkyl; n is 0, 1 or 2; and m is 1, 2 or 3; or pharmaceutically or veterinarily acceptable salts thereof; and

- (b) the second active agent is a leukotriene receptor antagonist.
- 2. (Original) The pharmaceutical composition of claim 1, wherein the first active agent is a non-glucocorticoid steroid having the chemical formula (I), wherein said multivalent organic dicarboxylic acid is SO<sub>2</sub>OM, phosphate or carbonate, wherein M comprises a counterion, wherein said counterion is H, sodium, potassium, magnesium, aluminum, zinc, calcium, lithium, ammonium, amine, arginine, lysine, histidine, triethylamine, ethanolamine, choline, triethanoamine, procaine, benzathine, tromethanine, pyrrolidine, piperazine, diethylamine, sulfatide

wherein  $R^2$  and  $R^3$ , which are the same or different, and are straight or branched ( $C_1$ - $C_{14}$ ) alkyl or glucuronide

- (Original) The pharmaceutical composition of claim 2, wherein said first active agent is dehydroepiandrosterone.
- (Original) The pharmaceutical composition of claim 2, wherein said first active agent is dehydroepiandrosterone-sulfate.
- (Original) The pharmaceutical composition of claim 1, wherein said leukotriene receptor antagonist is a montelukast, zafirlukast or pranlukast.

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 (Original) The pharmaceutical composition of claim 1, further comprising a ubiquinone or pharmaceutically or veterinarily acceptable salt thereof, wherein the ubiquinone has the chemical formula

wherein n is 1 to 12.

- (Original) The pharmaceutical composition of claim 1, wherein the pharmaceutical composition comprises particles of inhalable or respirable size.
- (Original) The pharmaceutical composition of claim 7, wherein the particles are about 0.01 μm to about 10 μm in size.
- (Original) The pharmaceutical composition of claim 7, wherein the particles are about 10 µm to about 100 µm in size.
- (Original) A kit comprising a delivery device and the pharmaceutical composition of claim 1.
- (Original) The kit of claim 10, wherein the delivery device is an aerosol generator or spray generator.
- (Original) The kit of claim 11, wherein the aerosol generator comprises an inhaler.
- (Original) The kit of claim 12, wherein the inhaler delivers individual premetered doses of the formulation.
- (Original) The kit of claim 12, wherein the inhaler comprises a nebulizer or insufflator.

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- 15. (Withdrawn) A method for reducing the probability of or treating asthma in a subject, comprising administering to a subject in need of such treatment a prophylactically or therapeutically effective amount of the pharmaceutical composition of claim 1.
- 16. (Withdrawn) A method for reducing the probability of or treating of chronic obstructive pulmonary disease in a subject, comprising administering to a subject in need of such treatment a prophylactically or therapeutically effective amount of the pharmaceutical composition of claim 1.
- 17. (Withdrawn) A method for treatment of respiratory, lung or malignant disorder or condition, or for reducing levels of, or sensitivity to, adenosine or adenosine receptors in a subject, comprising administering to a subject in need of such treatment a prophylactically or therapeutically effective amount of the pharmaceutical composition of claim 1.
- 18. (Withdrawn) The method of claim 17, wherein the disorder or condition comprises asthma, chronic obstructive pulmonary disease (COPD), cystic fibrosis (CF), dyspnea, emphysema, wheezing, pulmonary hypertension, pulmonary fibrosis, hyper-responsive airways, increased adenosine or adenosine receptor levels, adenosine hyper-sensitivity, infectious diseases, pulmonary bronchoconstriction, respiratory tract inflammation or allergies, lung surfactant or ubiquinone depletion, chronic bronchitis, bronchoconstriction, difficult breathing, impeded or obstructed lung airways, adenosine test for cardiac function, pulmonary vasoconstriction, impeded respiration, Acute Respiratory Distress Syndrome (ARDS), administration of adenosine or adenosine level increasing drugs, infantile Respiratory Distress Syndrome (infantile RDS), pain, allergic rhinitis, cancer, or chronic bronchitis.